In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: April 23, 2025

ANA BRUNO GARCIA,	*	
	*	No. 19-1927V
	*	
Petitioner,	*	Special Master Young
	*	
v.	*	
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Roberto E. Ruiz-Comas, RC Legal and Litigation Services LLC, Guaynabo, PR, for Petitioner.
Adam Nemeth Muffett, United States Department of Justice, Washington, DC, for Respondent.

DECISION ON ENTITLEMENT[1]

On December 19, 2019, Ana Bruno Garcia ("Petitioner") filed a petition for compensation in the National Vaccine Injury Compensation Program ("the Program")[2] alleging that the influenza ("flu") vaccine Petitioner received on December 29, 2017, caused her to suffer from "injuries, including meningoencephalitis." Pet. at ¶ 1, ECF No. 1. After carefully analyzing and weighing all the evidence presented in this case in accordance with the applicable legal standards,[3] I find that Petitioner has failed to provide preponderant evidence that the flu vaccine Petitioner received

[1] Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755 ("the Vaccine Act" or "Act"). Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

[3] While I have reviewed all of the information filed in this case, only those filings and records that are most relevant to the decision will be discussed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision.") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.*, 527 F. App'x 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.").

on December 29, 2017, caused her to develop "meningoencephalitis or possible Acute Disseminated Encephalomyelitis ("ADEM")." Pet'r's Mot. at 2, ECF No. 40. Accordingly, Petitioner is not entitled to compensation.

I. Procedural History

Petitioner filed her petition on December 19, 2019. Pet. On December 26, 2019, Petitioner filed Exhibits 1–12, which included a copy of Petitioner's U.S. Passport, medical records, and an affidavit from Petitioner. Pet'r's Exs. 1–12, ECF Nos. 6–7. The same day, she filed her statement of completion. ECF No. 8. On June 24, 2020, Petitioner filed an additional, legible copy of her immunization record. Pet'r's Ex. 13, ECF No. 13.

On December 14, 2020, Respondent filed his Rule 4(c) Report, recommending that compensation be denied. Resp't's Report, ECF No. 19. On July 14, 2021, Petitioner filed an expert report from Christian E. Schenk, M.D. Pet'r's Ex. 15, ECF No. 23. Petitioner filed a statement of completion on July 15, 2021. ECF No. 24. On November 12, 2021, Respondent filed expert reports from Michael Wilson, M.D., M.A.S., and S. Mark Tompkins, Ph.D., as well as their curriculum vitae and accompanying medical literature. Resp't's Ex. A, Tabs 1–8, B, ECF No. 26; Resp't's Ex. C, Tabs 1–5, D, ECF No. 27. Petitioner filed a rebuttal expert report from Dr. Schenk and accompanying medical literature on March 17, 2022, along with an expert report from Cristina Ramos, M.D. Pet'r's Exs. 16–17, ECF Nos. 29–30. On March 25, 2022, the Court received accompanying medical literature for Dr. Ramos' report, which was submitted on a portable storage disc. *See* ECF No. 32. On July 11, 2022, Respondent filed supplemental reports from Dr. Wilson and Dr. Tompkins with accompanying medical literature. Resp't's Exs. E, F, Tabs 1–9, ECF No. 33. On October 5, 2022, Petitioner filed a supplemental expert report from Dr. Ramos. Pet'r's Ex. 18, ECF No. 35.

On November 22, 2022, the parties filed a joint status report agreeing to submit the case for a ruling on the record. Joint Status Report, ECF No. 37. Petitioner submitted her motion for a ruling on the record on March 20, 2023. Pet'r's Mot. Respondent filed a response on May 19, 2023. Resp't's Resp., ECF No. 41. Petitioner filed a reply on July 20, 2023. Pet'r's Reply, ECF No. 44.

This matter is now ripe for consideration.

II. Factual Background

A. Medical Records

Prior to vaccination, Petitioner's medical history was significant for hypertension, diabetes, arthritis, hyperthyroidism, degenerative joint disease, cardiac arrhythmias, and anxiety. Pet'r's Ex. 3 at 29, 227, ECF No. 7-1; Pet'r's Ex. 8 at 2, 32, ECF No. 6-7; Pet'r's Ex. 11 at 5, ECF No. 6-10. Petitioner was 73 years old at the time of her flu vaccination on December 29, 2017. Pet'r's Ex. 2 at 2–3, ECF No. 6-2.

On December 29, 2017, Petitioner received the subject flu vaccination at Costco Pharmacy in Milford, Connecticut. *Id.* at 3. Seven days later, on January 5, 2018, Petitioner's son brought her to the emergency room ("ER") at Yale New Haven Health with symptoms of confusion, nausea, vomiting, abdominal pain, and tremors. Pet'r's Ex. 3 at 29. The medical report noted that she had no symptoms until the day prior to admission, when she was found to be "delirious" with a recorded fever of 104 degrees Fahrenheit. *Id.* at 39. Petitioner's children stated that Petitioner had received the flu shot one week prior to her appointment. *Id.* at 29. During the same time, Petitioner's children reported to be "down with a viral URI . . .(but no GI symptoms)." *Id.* Petitioner was admitted to the hospital, and a geriatric consult was ordered. *Id.* at 32. During her stay, Petitioner developed "progressive lethargy[,] followed by seizure activity and unresponsiveness." *Id.* at 33. She was intubated and moved to the intensive care unit ("ICU"). *Id.* Petitioner's temperature remained elevated, at times up to 104 degrees Fahrenheit, and an infectious disease consult was requested. *Id.*

On January 7, 2018, Zane Kevin Saul, M.D. performed an infectious disease consultation. *Id.* at 37–38. His impression notes identified fever and seizure symptoms and a need to rule out infectious meningoencephalitis. *Id.* at 38. Dr. Saul noted that Petitioner's "[p]ersistent fever curve [was] more suggestive of CNS fever." *Id.* He recommended a lumbar puncture, additional medications, an MRI when Petitioner was able to be moved, a neurological consultation, and to monitor temperatures and cultures. *Id.* The same day, Lawrence Beck, M.D. performed a neurological consultation. *Id.* at 39–40. Medical records indicate that Petitioner was intubated and sedated at the time of her examination and was therefore unresponsive to verbal or noxious stimuli. *Id.* at 39. Blood work revealed normal electrolytes; a peripheral white blood cell count of 9,900; hemoglobin at 12.1; CSF results showed 451 white blood cells, and glucose levels measured 123. *Id.* Petitioner's total protein was 129, her red cells measured 3, and no xanthochromia was noted. *Id.* A CT of Petitioner's brain showed a left temporal arachnoid cyst, but no acute abnormalities. *Id.* at 39–40. Petitioner was treated with broad-spectrum antibiotics and antiviral therapy. *Id.* Dr. Beck's impression was acute meningoencephalitis, due to an organism yet to be determined. *Id.*

Petitioner had a geriatric consult with Mithil Choksey, M.D. on January 8, 2018. *Id.* at 40. Dr. Choksey did not observe any discrete thoracic lymphadenopathy nor consolidated pneumonia, but felt Petitioner likely had advanced degenerative arthritis of the bilateral shoulders with a left-sided shoulder joint effusion. *Id.* at 45. He also observed scattered diverticulosis and an indeterminate 1.7 cm left adrenal nodule. *Id.* Dr. Choksey noted that Petitioner was likely encephalopathic from an ongoing infectious process and agreed with infectious and neurological work-ups. *Id.* The same day, Petitioner underwent an electroencephalogram ("EEG") with abnormal results, due to generalized slowing of the background rhythm consistent with diffuse cerebral dysfunction. Pet'r's Ex. 5 at 16, ECF No. 6-4. No focal or paroxysmal features were noted. *Id.*

On January 9, 2018, Petitioner had a neurology follow up with James Butler, M.D. Pet'r's Ex. 3 at 67. During this evaluation, Petitioner, who awakened to voice and light stimulation, followed simple commands, and moved both arms and legs. *Id.* Her grip strength was weak, but equal in both hands. *Id.* Geriatric progress notes from the same day listed "acute encephalopathy in the setting of-URI, seizures, [and] alteration in mental status [with a] working diagnosis [of] meningeal encephalitis." *Id.* Treatment plans included "possible intubation later in the day[, c]ontinue on board (sic) spectrum antibiotics and antivirals." *Id.*

Petitioner's January 10, 2018, laboratory results for West Nile, CMV, HSV, and Enterovirus were negative. *Id.* at 103. Critical care notes from the same date contain an impression of "[s]uspected encephalitis complicated by seizure and resp[iratory] failure." Pet'r's Ex. 3 at 72, 76.

On January 11, 2018, Dr. Butler noted Petitioner's improvement, despite complaints of headache and neck pain. Pet'r's Ex. 5 at 20, ECF No. 6-4. Her diagnosis remained meningoencephalitis, much improved, and Dr. Butler questioned whether there was a relationship between Petitioner's condition and her recent flu shot. *Id.* An MRI conducted on January 13, 2018, showed no evidence of infectious or inflammatory processes involving the cervical spine. Pet'r's Ex. 3 at 110. Petitioner showed multi-level degenerative changes, no significant canal stenosis or cord compression, and asymmetric right thyroid lobe enlargement incompletely characterized on exam. *Id.* Petitioner was discharged home with therapy services on January 16, 2018. *Id.* at 119. Her principal discharge diagnoses were acute encephalopathy, possible viral meningoencephalitis, and seizures. *Id.* Petitioner was hemodynamically stable and was ambulating with physical therapy prior to discharge. *Id.*

Goran Miljkovic, M.D. evaluated Petitioner for a follow-up visit on January 30, 2018. Pet'r's Ex. 9 at 4. Dr. Miljkovic noted viral encephalitis following the flu vaccination. *Id.* At the time of her evaluation, Petitioner was without headaches, fevers, or chills, or an altered mental status. *Id.* Her diagnosis remained encephalitis, with an unclear etiology- "possibly viral versus post-[flu] vaccination encephalitis." *Id.* Petitioner was advised to avoid the flu vaccine in the future. *Id.*

Petitioner was evaluated by neurologist Philip Barasch, M.D., on February 7, 2018. Pet'r's Ex. 5 at 17. Dr. Barasch noted Petitioner's diagnosis of encephalitis, with no clear etiology determined at the time of her hospital discharge. *Id.* at 16–17. On physical examination, Petitioner was alert and oriented and in no acute distress, had normal tone and strength in upper and lower extremities, mild imbalance, and no sensory loss to light touch bilaterally. *Id.* at 18–19. Dr. Barasch agreed with Petitioner's hospital diagnosis. *Id.* at 19. Dr. Barasch also noted that he had requested medical records from the hospital to determine the etiology of her meningoencephalitis. *Id.* In the interim, Petitioner was instructed to continue taking Levetracetam[4] 500 mg twice a day and began to taper off if she continued without any seizure activity. *Id.*

On February 21, 2018, Petitioner was discharged from home physical therapy after meeting stated goals, including "supervision or less with performing tub transfers for bathing," independent "supine to sit to stand transfers and indoor ambulation with appropriate assistive device," and ability to "ascend/descend stairs independently." Pet'r's Ex. 4 at 84–85.

Petitioner returned for a follow-up with Dr. Barasch on March 23, 2018. Pet'r's Ex. 5 at 12. Petitioner reported ongoing fatigue and weight loss, which Dr. Barasch thought might be due

[4] Levetiracetam is "an anticonvulsant administered orally as an adjunct in the treatment of partial and myoclonic seizures and idiopathic generalized epilepsy." *Dorland's Illustrated Medical Dictionary* (33rd ed. 2020) [hereinafter "*Dorland's*"].

to her seizure medication. *Id.* at 14. Blood work was ordered, and a taper off the Levetracetam was recommended. *Id.* Her diagnosis was viral encephalitis. *Id.*

On September 10, 2018, Petitioner saw Mitchell Matundan, M.D., an internal medicine specialist, for an initial evaluation. Pet'r's Ex. 11 at 2, ECF No. 6-10. Petitioner's physical examination revealed urinary incontinence, generalized aches (arthritis low back pain), and anxiety depressed mood with loss of interest. *Id.* at 4. Petitioner's neurological exam was normal. *Id.* Dr. Matundan's diagnoses for Petitioner were diabetes Type II and an adjustment disorder with anxiety. *Id.* at 5. On November 26, 2018, Petitioner returned to Dr. Matundan for evaluation of a rash that occurred after eating seafood. *Id.* at 8. Petitioner's neurological examination was normal. *Id.* at 9.

Petitioner saw Dr. Matundan for lab and follow-up appointments from February 2019 to May 2019. *Id.* at 13, 21, 25. Petitioner's neurological examinations were normal. *Id.* at 17, 22, 27.

On July 1, 2019, approximately one year and six months after the subject vaccination, Petitioner sought treatment with Palmira Martinez Romero, M.D., with the Bayamon Otolaryngology Group, for nasal congestion and loss of smell "since six months ago." Pet'r's Ex. 10 at 2, ECF No. 6-9. Petitioner also reported an altered sense of taste "since six months ago." *Id.* Dr. Romero noted that Petitioner was intubated "due to encephalitis after [flu] vaccine or viral, since no etiologic agent was identified." *Id.* Dr. Romero's assessment included anosmia, deviated nasal septum, chronic pansinusitis, and acute pharyngitis. *Id.* at 3. Dr. Romero prescribed Petitioner Fluticasone Propionate nasal suspension and Claritin. *Id.*

Petitioner saw Dr. Matundan for follow-up of laboratory testing on September 9, 2019. Pet'r's Ex. 11 at 35. Petitioner's neurological and musculoskeletal examinations were normal. *Id.* On October 15, 2019, Petitioner returned to Dr. Matundan with complaints of generalized aches, arthritis, low back pain, and gait difficulty. *Id.* at 42. Petitioner requested a prescription for a rollator stroller due to gait difficulty. *Id.* On December 3, 2019, Petitioner was reevaluated by Dr. Miljkovic, her infectious disease specialist, for seizure and encephalitis. Pet'r's Ex. 9 at 6. Petitioner described an absence of smell and taste, and Dr. Miljkovic indicated a possibility that her symptoms were the result of viral meningoencephalitis. *Id.* at 6–7. Dr. Miljkovic noted there was "[n]o ongoing infectious process," and instructed Petitioner to follow up with ENT and neurology. *Id.* at 7.

B. Petitioner's Affidavit

Petitioner submitted an affidavit that briefly summarized her condition and sequela. Pet'r's Ex. 12, ECF No. 6-11. She described "flu-like symptoms, chills, and general malaise" six days after she received her December 29, 2017, flu vaccine. *Id.* at ¶ 3. Believing that she may be having a stroke, Petitioner went by ambulance to Bridgeport Hospital in Connecticut with "abdominal pain, fever, a mild cough, tremors, nausea, vomiting, and confusion." *Id.* When she arrived at the hospital, she "had a very high fever, suffered a seizure and was transferred to the ICU where [she] was intubated and sedated." *Id.* at ¶ 4. She claimed that she was then diagnosed with viral meningoencephalitis after a lumbar spine exam. *Id.* She noted that while hospitalized, an infectious disease doctor advised her "to never repeat the [flu] vaccine, as it was very likely [her] meningoencephalitis was caused by the [flu] vaccine." *Id.* at ¶ 5. After months of physical

rehabilitation, Petitioner has "regain[ed] the ability to be independent again." *Id.* at ¶ 6. However, she still suffers from significant decreases in smell and taste sensitivity, memory loss, appetite, and weight loss, and constant fatigue. *Id.* at ¶ 7.

III. Expert Review

A. Petitioner's Experts

1. Christian E. Schenk, M.D.[5]

Dr. Schenk submitted two expert reports in this case. Pet'r's Ex. 15, ECF No. 23-1. He is board-certified in psychiatry and neurology, with experience as an expert witness in civil, criminal, and medical malpractice cases since 2013. *Id.* at 1. Currently, Dr. Schenk works with patients, teaches, and conducts research at the University of Puerto Rico, School of Medicine. *Id.* He has a general and behavioral neurology practice wherein he sees patients "at both inpatient and outpatient settings." *Id.*

In Dr. Schenk's first submitted report, he discussed Petitioner's medical history with a focus on her January 2018 hospitalization. *Id.* He inserted direct quotes from the medical record that detail Petitioner's initial symptoms when she presented to the hospital on January 5, 2018, laboratory and diagnostic tests, and Petitioner's course of treatment. *Id.* at 1–8. Dr. Schenk then reviewed several differential diagnoses, including encephalopathy, stroke, vaccine-related neuro-inflammatory disorders, and the presumptive diagnosis of meningoencephalitis. *Id.* at 9. Petitioner's "neck rigidity, nausea, vomiting and fever, along with signs of encephalitis with the presence of neurological symptoms and encephalopathy or alteration of consciousness and seizures." *Id.* at 10. Dr. Schenk also cited Petitioner's CSF analysis as evidence of meningoencephalitis. *Id.* Although an extensive infectious disease panel was conducted with no positive results, Petitioner's quick recovery contributed to a "final presumptive diagnosis [of] viral meningoencephalitis." *Id.* Dr. Schenk noted that vascular disorders were considered, but Petitioner's "neuroimaging with MRI [did] not report evidence of previous ischemic lesions or signs suggestive of previous hemorrhagic stroke." *Id.*

Dr. Schenk described encephalitis as "a severe inflammatory disorder of the brain with many possible causes and a complex differential diagnosis." *Id.* (citing Pet'r's Ex. 16-23, ECF No. 29-23).[6] He noted that the condition is "frequently caused by a virus," and "causes focal or multi-focal neurological deficits and [frequent] seizure activity." *Id.* Meningoencephalitis is characterized by clinical symptoms or findings, "which would be neck rigidity and pain, sensitivity to light, irritability, altered mental status, fevers, chills, nausea and vomiting, all which develop as signs of meningeal irritation." *Id.* (citing Pet'r's Ex. 16-10, ECF No. 29-10).[7] Dr. Schenk noted that Petitioner's presentation was consistent with "acute and often rapidly progressive" multifocal

[5] Dr. Schenk did not submit a curriculum vitae in this case. His qualifications are briefly summarized in his initial report and are referenced here.

[6] Francesc Graus et al., *A Clinical Approach to Diagnosis of Autoimmune Encephalitis*, 15 LANCET NEUROLOGY 391 (2016).

[7] Diederik van de Beek et al., *Clinical Features and Prognostic Factors in Adults with Bacterial Meningitis*, 351 NEW ENG. J. MED. 1849 (2004).

neurological deficits. *Id.* at 11 (citing Pet'r's Ex. 3 at 5, 28). He included in his report a chart that outlines the Diagnostic Criteria for Encephalitis and Encephalopathy of Presumed Infectious or Autoimmune Etiology. *Id.* Altered mental status lasting less than 24 hours with no alternative cause identified was the only major required criterion. *Id.* The chart also included minor criteria and noted that three or more are "required for probable or confirmed encephalitis." *Id.* Dr. Schenk detailed Petitioner's individual symptoms of nausea and vomiting, which are indicative of "increased intracranial pressure and also[] meningitis;" altered mental status or "acute deterioration of consciousness caused by an internal or provoking condition;" a tremor, in Petitioner's case, most likely a "physiological response to an acute process, fever, or related to seizures;" fever; and neck pain. *Id.*

Given Petitioner's "presentation of a monophasic Central Nervous System (CNS) inflammatory syndrome of unknown etiology," Dr. Schenk opined that "acute demyelinating encephalomyelitis (ADEM) must be considered." *Id.* This is especially true for Petitioner, "in view of prior administration of a vaccine." *Id.* at 12. ADEM presents similarly to viral encephalitis, but "encephalopathy is less frequent [in adults] and the clinical presentation is usually dominated by long tract involvement (corticospinal tract signs and symptoms)." *Id.* Dr. Schenk explained that "an autoimmune response is the cause of the inflammatory reaction, and [] a trigger such as a viral or bacterial infection or a vaccine, is considered in the majority of cases." *Id.* He asserted the timeframe "for ADEM to occur after vaccination (2-30 days)" and explained that in Petitioner's case, "[t]he presence of close sick contacts prior to infection, most likely viral infections, were accounted for with a negative viral panel testing." *Id.* (citing Pet'r's Ex. 16-62, ECF No. 29-62;[8] Pet'r's Ex. 3 at 64).

Dr. Schenk continued to explain that ADEM, "also known as postinfectious encephalomyelitis, is an autoimmune demyelinating disease of the central nervous system and may occur as an immunologically mediated para-infectious phenomenon following a variety of infections or after vaccination." *Id.* It is typically characterized by "multifocal inflammatory lesions, principally affecting the white matter of the CNS." *Id.* (citing Pet'r's Ex. 16-49, ECF No. 29-49).[9] He proposed one pathogenic mechanism that occurs when "myelin autoantigens such as myelin basic protein, proteolipid protein, and myelin oligodendrocyte protein share antigenic determinants with those of an infecting pathogen. Antiviral antibodies or a cell-mediated response to the pathogen cross-react with the myelin autoantigens, resulting in [postinfectious neurological syndromes]." *Id.* at 13.

ADEM is a "diagnosis of exclusion," but it "require[s] there to be an encephalopathy." *Id.* at 14. Dr. Schenk identified ADEM onset symptoms as "low-grade fever, headache and meningism preceding the development of drowsiness and encephalopathy which may progress to stupor and coma, as it evolves rapidly over hours to days." *Id.* The diagnosis is considered more readily in the context of recent illness or vaccination, and "[t]he rare post[-]vaccinal cases typically follow a

[8] Romain Sonneville et al., *Update on Investigation and Management of Postinfectious Encephalitis*, 23 CURRENT OP. NEUROLOGY 300 (2010).
[9] Siobhan Leary et al., NEUROLOGY: A QUEEN SQUARE TEXTBOOK 439–40 (Robin Howard et al. eds., 2nd ed. 2016).

primary rather than revaccination." *Id.* (citing Pet'r's Ex. 17-34, ECF No. 29-29).[10] ADEM is generally diagnosed by neuroimaging, especially MRI, and should be performed when ADEM is suspected. *Id.* Dr. Schenk noted that Petitioner did not receive a brain MRI during her hospitalization. *Id.* at 15. It could not be performed during her time in critical care "and later was considered not important once the resolution of symptoms and no seizure recurrence, after a follow up head CT scan was found without interval changes." *Id.* Dr. Schenk acknowledged that "ADEM after vaccination is a rare complication in children and adults," but "[m]ore recent surveillance studies have found little or no association between ADEM and immunization." *Id.* at 17 (citing Pet'r's Ex. 16-56, ECF No. 29-56;[11] Pet'r's Ex. 16-34, ECF No. 29-34;[12] Pet'r's Ex. 16-7, ECF No. 29-7).[13]

Dr. Schenk concluded that "[t]he signs and symptoms [Petitioner] presented during the first three days of hospitalization were consistent with the diagnosis of acute encephalitis." *Id.* at 18. He noted that "[c]linical and laboratory testing did not reveal a viral pathogen that would have caused the [meningoencephalitis.]" *Id.* While "[e]xamining mechanistic evidence to assess causation remains a challenge," Dr. Schenk opined that "[t]he cause of [Petitioner's] acute encephalitis is most likely due to an autoimmune reaction after a trigger such as administration of the [flu] vaccine days prior to the events." *Id.* Additionally, despite the "relatively short" duration of Petitioner's symptoms, ADEM "still remains the most acceptable diagnosis to consider in this patient." *Id.*

In a supplemental report, Dr. Schenk expressed agreement with "the clinical presentation description of an acute meningoencephalitis," but noted that "the exact etiological agent or trigger for the inflammatory process could not be detected." Pet'r's Ex. 16 at 1, ECF No. 29-1. Although there were some tests done to identify a possible pathogen, all results were negative, "and an infectious etiology could not be completely ruled out." *Id.* Dr. Schenk noted that Petitioner's MRI did not show signs of ADEM and that her "CSF profile [was] atypical for ADEM." *Id.* He continued that "[a]ntecedent viral infections or vaccinations have been suggested as presenting an antigenic challenge" leading to ADEM. *Id.* He suggested that molecular mimicry could be involved in Petitioner's case, but deferred to other experts versed in immunology. *Id.*

Dr. Schenk opined that Petitioner "most likely had a delayed inflammatory neurological syndrome, either a post-infectious neurological syndrome or an adverse event following immunization." *Id.* at 2. He maintained that there is a differential between "an acute meningoencephalitis due to either a vaccine or infectious viral or bacterial agent, and ADEM after immunization." *Id.* Although Dr. Schenk cited "the timing of the vaccine and the presentation of seizures and encephalopathy" to describe Petitioner's progression as "a clinical presentation," he

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[10] William Huynh et al., *Post-Vaccination Encephalomyelitis: Literature Review and Illustrative Case*, 15 J. CLINICAL 1315 (2008).
[11] Margaret Ryan et al., *Revisiting Influenza Vaccination Exemption*, 24 EMERGING INFECTIOUS DISEASES 1947 (2018).
[12] Jorge D. Machicado et al., *Acute Disseminated Encephalomyelitis Following Seasonal Influenza Vaccination in an Elderly Patient*, 20 CLINICAL VACCINE 1485 (2013).
[13] Roger Baxter et al., *Acute Demyelinating Events Following Vaccines: A Case-Centered Analysis*, 63 CLINICAL INFECTIOUS DISEASES 1456 (2016).

also described her case as atypical "in adult presentation and with a relatively quick recovery." *Id.* He also noted that her recovery was not facilitated by "any treatment for ADEM such as corticosteroids or immunoglobulin." *Id.* In conclusion, Dr. Schenk opined that Petitioner developed delayed meningoencephalitis, and much less likely an acute demyelinating event such as ADEM. *Id.* In either scenario, "a post-vaccination reaction is considered more likely," despite "laboratory results [that] point toward a bacterial or fungal etiology." *Id.* If Petitioner "had an infectious etiology for her symptoms, in the frame after her [flu] vaccination, [it] would rather be a coincidence." *Id.*

2. Cristina Ramos-Romey, M.D.[14]

Cristina Ramos-Romey received her medical degree from the University of Puerto Rico's Medical Sciences Campus. Pet'r's Ex. 17 at 1, ECF No. 30-1. She specialized in internal medicine with a subspecialty in geriatrics at the University District Hospital. *Id.* Dr. Ramos also received her subspecialty in allergy and immunology at Pennsylvania State University, Hershey Medical Center. *Id.* She is board certified in internal medicine, geriatrics, and allergy and immunology. *Id.* Dr. Ramos is the Allergy and Immunology Fellowship Program Professor at the University of Puerto Rico School of Medicine. *Id.* She is the lead immunology researcher at the Fundación de Investigación research facility. *Id.*

In her first report, Dr. Ramos summarized Petitioner's medical records and stated that she "will defer to Dr. Schenk [] on the detailed evaluation and diagnostic criteria of [Petitioner's] neurological disorder and differential diagnosis." *Id.* at 5. As to causation, Dr. Ramos asserted that "[a]lthough we have already established that it is more likely that her symptoms were caused by an infection, we cannot discard the possibility that [Petitioner's] symptoms were caused by an adverse reaction to the [flu] vaccine, due to the proximity of the onset of symptoms and her recent [flu] vaccination." *Id.* at 7–8.

Dr. Ramos asserted that "[t]he term molecular mimicry and immune cross-reaction is a theory that has been accepted as a possible and viable explanation of how vaccines may cause neurological disease." *Id.* at 8. She then explained the general concept of molecular mimicry, "as a process in which there is immune cross-reactivity due to structural homology between pathogens and self-antigens." *Id.* Medical researchers have discovered a "massive overlap" of viral and bacterial peptides, which are shared with the human genome." *Id.* This overlap will not likely result in autoimmunity, except "in the setting of impaired tolerance, such as environmental causes and genetic predisposition to autoimmune disease, this homology may induce autoimmunity." *Id.* (citing Pet'r's Ex. 17-11, ECF No. 32).[15] Dr. Ramos described a study done with rabbit tissue samples that were exposed to a viral peptide and produced a histology "consistent with allergic encephalomyelitis." *Id.* at 8–9 (citing Pet'r's Ex. 17-8, ECF No. 32).[16] She noted that other

[14] Dr. Ramos did not submit a curriculum vitae in this case. Her qualifications are briefly summarized in her initial report and are referenced here.

[15] Darja Kanduc, *Quantifying the Possible Cross-Reactivity Risk of an HPV16 Vaccine*, 8 J. EXPERIMENTAL THERAPEUTICS ONCOLOGY 65 (2009).

[16] R.S. Fujinami et al., *Molecular Mimicry in Virus Infection: Crossreaction of Measles Virus Phosphoprotein or of Herpes Simplex Virus Protein with Human Intermediate Filaments*, 80 PROCS. NAT'L ACAD. SCIS. U.S. 2346 (1983).

"[s]tudies have also shown molecular mimicry resulting in diseases such as uveitis, myocarditis and myasthenia gravis due to viral proteins." *Id.* at 9 (citing N. Neu et al.;[17] Pet'r's Ex. 17-12, ECF No. 32;[18] Pet'r's Ex. 17-13, ECF No. 32;[19] VK Singh et al.).[20] Consequently, "[t]he concept of molecular mimicry has been widely accepted as a proven concept and is considered to be one of the mechanisms in which viral or bacterial infections can result in the development or worsening of autoimmune disease." *Id.* at 10.

In addition to molecular mimicry, Dr. Ramos asserted other "proposed mechanisms for viral and vaccine-induced autoimmunity includ[ing] bystander activation, epitope spreading, [] and polyclonal activation." *Id.* She described these processes briefly as follows: "Bystander activation occurs when T cells recognize viral particles and are activated. Activation lead (sic) to the secretion of inflammatory mediators that may damage the surrounding tissues. Once damaged the self-epitopes are released and presented to autoreactive T cells and mediate future damaged, this is known as epitope spreading." *Id.* Dr. Ramos further explained that "[m]olecular mimicry occurs when T cells bearing [receptors] specific to epitopes derived from foreign pathogens (e.g., viruses) are activated during an infection and cross-react with self-antigens inducing autoimmune diseases." *Id.* (citing Pet'r's Ex. 17-14, ECF No. 32).[21] She noted the postulation by some researchers that "although molecular mimicry is a common event, it only leads to autoimmunity disease when it takes place in the context of chronic local inflammation, presentation of self-antigens and a sufficient number of autoreactive T cells." *Id.* at 11 (citing Pet'r's Ex. 17-19, ECF No. 32).[22]

Dr. Ramos next turned to studies of molecular mimicry "to explain the mechanisms through which vaccination can cause or worsen neurological conditions." *Id.* She noted an increased concern in the medical community for post-vaccination autoimmune diseases such as Guillain-Barré Syndrome ("GBS") and narcolepsy following mass flu vaccinations in 2009. *Id.* Specifically, US studies done following the 2009 H1N1 pandemic revealed "consistent epidemiologic evidence demonstrating an increased risk of GBS following the 2009 H1N1 vaccines across different populations," and "provid[ing] strong evidence for a causal relationship."

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[17] N Neu et al., *Cardiac Myosin Induces Myocarditis in Genetically Predisposed Mice*, 139 J. IMMUNOLOGY 3630 (1987). Petitioner failed to file this article with the Court, and as a result, I am unable to consider it within the context of Dr. Ramos' discussion or incorporate it into my analysis and findings.

[18] C.J. Gauntt et al., *Coxsackievirus-Induced Chronic Myocarditis in Murine Models*, 16 EUR. HEART J. 56 (1995).

[19] Schulze K. Schultheiss, *The Role of the ADP/ATP Carrier in the Pathogenesis of Viral Heart Disease*, 16 EUR. HEART J. 64 (1995).

[20] VK Singh et al., *Molecular Mimicry Between a Uveitopathogenic Site of S-antigen and Viral Peptides. Induction of Experimental Autoimmune Uveitis in Lewis Rats*, 144 J IMMUNOLOGY 1282 (1990). Petitioner failed to file this article with the Court, and as a result, I am unable to consider it within the context of Dr. Ramos' discussion or incorporate it into my analysis and findings.

[21] El Rosario University Press, AUTOIMMUNITY: FROM BENCH TO BEDSIDE (Juan-Manuel Anaya et al. eds., 1st ed. 2013).

[22] Silva Markovic-Plese et al., *High Level of Cross-Reactivity in Influenza Virus Hemagglutinin-Specific CD4+ T-Cell Response: Implications for the Initiation of Autoimmune Response in Multiple Sclerosis*, 169 J. NEUROIMMUNOLOGY 31 (2005).

Id. at 10–11 (quoting Pet'r's Ex. 17-24, ECF No. 32).[23] Although vaccines differ from their viral counterparts, they "have viral protein subunits that may activate self-reactive T cells, especially if the patient has had prior infection with the virus." *Id.* at 11. Dr. Ramos mentioned reports of post-vaccination encephalitis and ADEM following rabies and Japanese encephalitis virus vaccines, but she acknowledged that "[w]ith the development of safer vaccines, the incidence of post-vaccinal encephalomyelitis has decreased." *Id.* She also mentioned the Topplak et al.[24] study, where "researchers found an increased level of autoantibodies or appearance of new autoantibodies in up to 15% of healthy individuals" one month post flu vaccination. *Id.* (citing Pet'r's Ex. 17-27, ECF No. 32). While the authors "did not find clinical significance to these autoantibodies," Dr. Ramos asserted that their increased presence "is of concern for the possibility of developing an autoimmune disease post-vaccination, especially with an underlying condition or genetic predisposition." *Id.* An appropriate temporal relationship "between vaccine injection and subsequent activation of an autoimmune condition such as ADEM could be coincidental. Alternatively, it could reflect a causal association revealing a biological link." *Id.*

In the present case, Dr. Ramos opined there is "a logical sequence of events and the timeline of [Petitioner's] symptoms consistent with the presentation of neurological complications following vaccination, reported in the literature to be approximately [two] weeks after vaccination." *Id.* at 12. Petitioner's "lack of previous symptoms, the evolution of symptoms, and clinical presentation" support a causal connection." *Id.* Dr. Ramos also noted that Petitioner's treaters considered whether her vaccination was related to the development of her symptoms. *Id.* She noted that an infectious process or a cerebrovascular event "were evaluated and excluded by the treating physicians." *Id.* Relying on "convincing evidence in the literature that vaccination with [flu] vaccine can cause neurological symptoms ranging from optic neuritis, ADEM, and GB," Dr. Ramos concluded that "there is sufficient evidence to support the conclusion that the [Petitioner's] symptoms were caused by the [flu] vaccine." *Id.*

Following the filing of Respondent's expert reports, Dr. Ramos submitted a supplemental expert report reiterating that vaccine-induced injury must be considered in this case "after an infectious etiology was out by the treating physician." Pet'r's Ex. 18 at 1, ECF No. 35-1. Her second report also followed Dr. Schenck's supplemental report and acknowledged his revised opinion that "the clinical presentation of [Petitioner] does not fully support the diagnosis of ADEM." *Id.* Dr. Ramos then questioned whether the specific vaccine Petitioner received is associated with encephalitis. *Id.* She noted that "[l]arge cohort studies have not shown an increase in the risk of neurological complications after [flu] vaccine;" however, case reports "are evidence of patients that have developed neurological and autoimmune disease post vaccination." *Id.* Dr. Ramos again noted that "[a]dditional studies to determine the clinical implications of [increased numbers of autoantibodies post flu vaccination] are needed." *Id.* at 2. In her final report, Dr. Ramos stated that she "cannot in sound medical judgment state that vaccination is the most probable cause of the [Petitioner's] neurological presentation, but we cannot in all certainty exclude the possibility that her symptoms were caused by the vaccine." *Id.* She maintained her initial assertion that

[23] Daniel A. Salmon et al., *Did the Influenza A (H1N1) 2009 Monovalent Inactivated Vaccines Increase the Risk for Guillain-Barré syndrome?*, 9 EXPERT REV. CLINICAL IMMUNOLOGY 795 (2013).
[24] N. Toplak et al., *Autoimmune Response Following Annual Influenza Vaccination in 92 Apparently Healthy Adults*, 8 AUTOIMMUNITY REVS. 134 (2008).

Petitioner's "timeline of the onset of her symptoms does support the theory of a vaccine induce[d] complication." *Id.* She added that "all [agree] that infectious causes are the most common causes of meningoencephalitis, and it is not surprising and should not be considered conclusive of an infectious process that the treating physicians treated the patient with antivirals and antimicrobials upon admission." *Id.* Without an alternative plausible cause, the temporal relationship between Petitioner's vaccination and neurological condition, Dr. Ramos argued that "[w]e cannot exclude the possibility that [Petitioner's] neurological condition was attributed to the [flu] vaccine." *Id.* She concluded that "[t]he clinical implications of eliciting and (sic) autoimmune response in genetically predisposed individuals cannot be ignored. It is [her] opinion that the treating physicians excluded other causes of [Petitioner's] neurological deterioration and a vaccine related adverse event following the [flu] vaccine is a more probable cause of [Petitioner's] symptoms." *Id.* at 2–3.

B. Respondent's Experts

1. Michael Wilson, M.D.

Dr. Wilson received his medical degree from the University of California, San Francisco School of Medicine ("UCSF"). Resp't's Ex. B at 1, ECF No. 26-10. He completed his neurology residency at Harvard Neurology Residency Program at Massachusetts General Hospital and Brigham and Women's Hospital. *Id.* Dr. Wilson has completed fellowships in neuro-infectious diseases, virology, and metagenomics at Massachusetts General, National Emerging Infectious Diseases Laboratories at Boston University School of Medicine, and UCSF School of Medicine, respectively. *Id.* He is board certified in neurology with subspecialty training in neuro-infectious diseases and neuroimmunology. Resp't's Ex. A at 1, ECF No. 26-1. He is currently the Director of the UCSF Center for Encephalitis and Meningitis, a clinic where he "diagnose[s] and treat[s] patients with a variety of neuroinflammatory disorders ranging from autoimmune diseases like multiple sclerosis and neuromyelitis optica to infectious causes of meningitis and encephalitis." *Id.* Dr. Wilson also completes "[four] weeks of inpatient neurology per year at Zuckerberg San Francisco General Hospital" and commonly encounters patients with acute meningoencephalitis. *Id.* He is also an associate professor of neurology at UCSF in the Division of Neuroimmunology and Glial Biology and a researcher that "has pioneered the development of metagenomic next-generation sequencing to diagnose neurologic infections in patients with meningitis, encephalitis and other neuroinflammatory conditions." *Id.* His research also includes the development of "comprehensive autoantibody and viral antibody discovery assays to search for antigenic targets and triggers of neuroinflammatory diseases, including multiple sclerosis and autoimmune encephalitis." *Id.* Dr. Wilson has been published in the *New England Journal of Medicine* in addition to several other top peer-reviewed journals. *Id.*

After a brief summary of Petitioner's medical course, Dr. Wilson agreed "with the [P]etitioner's doctors and [] expert that [she] suffered from an acute meningoencephalitis given the rapid onset of fever, confusion, focal neurologic signs (i.e., word finding difficulty)[,] and seizure in the setting of a highly inflammatory CSF profile." *Id.* at 1–2 (citing Resp't's Ex. A, Tab 1, ECF No. 26-2).[25] However, he cautioned, meningoencephalitis "is not a diagnosis[; i]t is a

[25] A. Venkatesan et al., *Case Definitions, Diagnostic Algorithms, and Priorities in Encephalitis: Consensus Statement of the International Encephalitis Consortium*, 57 CLINICAL INFECTIOUS DISEASES 1114 (2013).

syndrome that can be caused by more than 100 different infectious and non-infectious etiologies." *Id.* at 3. Dr. Wilson noted that treaters "frequently fail to identify the etiologic agent in a broad array of encephalitis syndromes," and in Petitioner's case, no definitive diagnosis was made. *Id.* (citing Resp't's Ex. A, Tab 1; Resp't's Ex. A, Tab 2, ECF No. 26-3;[26] Resp't's Ex. A, Tab 3, ECF No. 26-4).[27] Nonetheless, Dr. Wilson agreed with Petitioner's treaters that an infectious meningoencephalitis "is much more likely than a non-infectious etiology, including vaccine-associated ADEM." *Id.* Petitioner's testing of infectious agents was limited to a small number, and Dr. Wilson asserted that "negative results for this limited number of pathogens by no means 'rules out' an infectious etiology." *Id.* He continued that it is still possible to "assess whether the patient likely had an infectious or non-infectious cause of her meningoencephalitis," even where the testing is non-diagnostic. *Id.*

Dr. Schenk initially opined that Petitioner suffered from ADEM; however, Dr. Wilson noted that Petitioner "was not known to have 'the diagnostic hallmark of ADEM . . . , the demonstration of scattered, focal or multifocal (disseminated) areas of inflammation and demyelination within cerebral subcortical and deep cortical white matter." *Id.* (citing Resp't's Ex. A, Tab 7, ECF No. 26-8;[28] Resp't's Ex. A, Tab 8, ECF No. 26-9).[29] He concluded that there is insufficient information to definitively classify her course as ADEM. *Id.* Additionally, Dr. Wilson noted that despite the lack of a brain MRI, Petitioner's "profile was not consistent with what is seen in the vast majority of ADEM cases." *Id.* at 4. Petitioner made a rapid and "dramatic" recovery without receipt of any of the immunosuppressant medications "typically required to treat ADEM." *Id.* Her CSF profile was not consistent with ADEM cases, and specifically, her neutrophil cell count was elevated. *Id.* Dr. Wilson explained that in ADEM cases, the elevation is usually with respect to lymphocytes, not neutrophils, while "[n]eutrophils are typically elevated when a patient is fighting a bacterial or fungal infection or in very early viral meningoencephalitis." *Id.* (citing Resp't's Ex. A, Tab 1). Petitioner also "had elevated systemic inflammatory markers (elevated white blood cell count, erythrocyte sedimentation rate and procalcitonin) which are not elevated in the context of ADEM," combined with her high fever and intermittent hypotension, which are also "consistent with an infectious etiology." *Id.* Although Dr. Wilson asserted that there is overwhelming evidence that Petitioner did not suffer from ADEM, he also argued that "she had another potential temporally proximate trigger for ADEM: she was exposed to her children who had viral upper respiratory infections in the week prior to her illness." *Id.* (citing Resp't's Ex. A, Tab 8). He acknowledged that "[t]here are rare reports of ADEM occurring in close temporal association with different vaccines, but as the [P]etitioner's expert notes, evidence for an increased risk of ADEM in association with vaccines in general is scant, including for [flu] vaccines." *Id.* Dr. Wilson also acknowledged that the timing of Petitioner's symptom onset approximately one week post vaccination "is within the accepted range during which immune-mediated vaccine

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[26] Prashanth S. Ramachandran & Michael R. Wilson, *Metagenomics for Neurological Infections - Expanding Our Imagination*, 16 NATURE REVS. NEUROLOGY 547 (2020).

[27] Carol A. Glaser et al., *In Search of Encephalitis Etiologies: Diagnostic Challenges in the California Encephalitis Project, 1998-2000*, 36 CLINICAL INFECTIOUS DISEASES 731 (2003).

[28] James J. Sejvar et al., *Encephalitis, Myelitis, and Acute Disseminated Encephalomyelitis (ADEM): Case Definitions and Guidelines for Collection, Analysis, and Presentation of Immunization Safety Data*, 25 VACCINE 5771 (2007).

[29] McGraw-Hill Education, ADAMS AND VICTOR'S PRINCIPLES OF NEUROLOGY (Andrew Moyer & Kim J. Davis eds., 11th ed. 2019).

complications occur." *Id.* at 5. Instead, Dr. Wilson argued that Petitioner's medical history, clinical presentation, and laboratory workup all "argues strongly for her having an undiagnosed infectious meningoencephalitis and not ADEM." *Id.* at 4.

In Dr. Wilson's supplemental report, he noted Dr. Schenk's agreement with his assessment of Petitioner's condition, insofar as it is inconsistent with ADEM and "could very well have been" infectious meningoencephalitis or even a bacterial infection that caused an inflammatory CNS reaction. Resp't's Ex. E at 1, ECF No. 33-1. Dr. Wilson contemplated that, "[i]f we discount the ADEM diagnosis, we are left wondering what link – if any – exists between [flu] vaccination and meningoencephalitis." *Id.* at 2. He acknowledged Dr. Schenk's assessment of case reporting of nervous system disorders, and how he acknowledged Dr. Wilson's previous assertion that "these are only case studies and the official surveillance has not found an association with the vaccine." *Id.* (quoting Pet'r's Ex. 15 at 2). Dr. Schenk's observation that the timing of the vaccination "would rather be a coincidence" was dismissed by Dr. Wilson as "not a substantive argument for affirmatively linking a vaccination to a neurologic event." *Id.* (quoting Pet'r's Ex. 15 at 2). Dr. Wilson reiterated that "[a]t the time of the vaccination, [P]etitioner was an elderly woman with multiple medical co-morbidities, including advanced age, hypertension and diabetes mellitus, who also had recent sick contacts." *Id.* He explained that "[t]hese are all risk factors for an infectious meningoencephalitis from a variety of pathogens so for her to develop an infectious meningoencephalitis at this time would not just be a 'coincidence'" *Id.* Dr. Wilson also noted that Petitioner filed "more than 100 associated exhibits [], the majority of which are not individually cited in their opinions. *Id.* at 1. (citing Pet'r's Exs. 16-1–16-69, ECF No. 29; Pet'r's Exs. 17-2–17-39, ECF No. 32). He concluded that "the expansive literature cited by the [P]etitioner's experts is not responsive to this case, and we are left with isolated case reports to speculate about any potential link between the [P]etitioner's condition and the [flu] vaccine she received." *Id.* at 2.

2. Stephen M. Tompkins, Ph.D.

Dr. Tompkins received his Ph.D. in immunology from Emory University. Resp't's Ex. D at 1, ECF No. 27-7. He completed post doctorate training in immunology and virology at Northwestern University and the Center for Biologics Evaluation and Research at the United States Food and Drug Administration. *Id.* Dr. Tompkins' fellowships "focused on immunologic mechanisms of induction of autoimmune disease, specifically interrogating antigen- and virus-induced models of experimental autoimmune encephalomyelitis[;] and . . . understanding the immune response to influenza infection and vaccination". Resp't's Ex. C at 1, ECF No. 27-1. He is currently Professor of Infectious Diseases in the Center for Vaccines and Immunology at the University of Georgia and conducts research focused on "understanding the interactions of [flu] virus and [flu] vaccines with the host." *Id.* Dr. Tompkins is an *ad hoc* reviewer for the National Institutes of Health ("NIH") study sections and scholarly journals in the fields of virology and immunology. *Id.*

Dr. Tompkins reviewed Petitioner's medical record to complete his report; however, he did "not comment on [Petitioner's] diagnosis and [] instead refer[red] to the expert report provided by [Dr. Wilson]." *Id.* at 4. In response to Dr. Schenk, Dr. Tompkins answered two questions: "1) Is inactivated [flu] vaccine associated with meningoencephalitis or ADEM? [and] 2) Is there an alternative explanation for the onset of disease?" *Id.* As to the first question, Dr. Tompkins answered "[n]o." *Id.* He argued that, notwithstanding Dr. Schenk's reference to "literature

support[ing] evidence of immune-mediated inflammatory brain disorders following vaccination in a wide spectrum of vaccines," the inactivated flu vaccine bears no relationship to that group. *Id.* (citing Pet'r's Ex. 15 at 16). Dr. Tompkins then shifted to Dr. Schenk's reliance on the Institute of Medicine's ("IOM") assessment that the available "epidemiologic evidence [is] insufficient and mechanistic evidence [is] weak for establishing a causal association between [flu] vaccination and encephalitis or ADEM." *Id.* (quoting Pet'r's Ex. 15 at 17). Dr. Tompkins acknowledged that this was "a reasonable representation of the findings of the IOM committee[;]" however, "it fail[ed] to consider the basis for these assessments." *Id.* According to Dr. Tompkins, the studies referenced by the committee "utilized passive surveillance systems and did not have unvaccinated comparison populations." *Id.* Furthermore, "[m]echanistic evidence of a possible association between [flu] vaccination and ADEM is entirely based upon reports of temporal associations and rare associations between [flu] infection and ADEM." *Id.* Dr. Tompkins also criticized Dr. Schenk's reliance on VAERS "due to the inherent limitations of passive surveillance." *Id.* at 5. Specific to ADEM, Dr. Tompkins cited Baxter et al.[30] as a work that "provides compelling evidence that [the flu] vaccination is not associated with ADEM." *Id.* (citing Resp't's Ex. C, Tab 3, ECF No. 27-4).

In response to the second question, Dr. Tompkins discussed Shukla et al.,[31] "[a]n assessment including clinical epidemiology and diagnostic evaluation of aseptic meningitis in the United States [that showed] 81% of etiologies remained unknown." *Id.* (citing Resp't's Ex. C, Tab 4, ECF No. 27-7). He noted other studies with similar percentages, including Aldriweesh et al.,[32] with a 60% pathogen identification rate in aseptic meningitis patients. *Id.* (Resp't's Ex. C, Tab 5, ECF No. 27-6). The literature suggests that "[b]ased upon the rate of undiagnosed viral infections associated with meningoencephalitis, it is probable that a viral infection was not detected." *Id.* at 6. Dr. Tompkins argued that this is consistent with the present case. *Id.* He noted that Petitioner's exposure to "the reported infections by two children the week before onset of symptoms," Petitioner's "gastrointestinal symptoms and URI [are] indicative of a viral infection [as] the most likely cause of [Petitioner's] meningoencephalitis." *Id.* (citing Pet'r's Ex. 1 at 29, 27, 33).

Despite ultimately discounting ADEM as Petitioner's correct diagnosis, Dr. Schenk's expert reports discussed the condition in depth. *See* Pet'r's Exs. 15–16. Consequently, Dr. Tompkins authored a supplemental report wherein he discussed "the likelihood that the [flu] vaccine was associated with onset of ADEM." Resp't's Ex. F at 2, ECF No. 33-2. Dr. Tompkins clarified that he was not conceding that Petitioner "developed ADEM following receipt of the [flu] vaccine." *Id.* Indeed, he reasoned that "[b]oth Dr. Wilson and Dr. Schenk note[d] that ADEM was unlikely," and reiterated that he would defer to Dr. Wilson's opinion on diagnosis. *Id.*

Dr. Tompkins opined that there is no evidence "that the 2017-2018 Afluria Quadrivalent [flu] vaccine is associated with ADEM," nor is there "evidence of molecular mimicry by the 2017-2018 Afluria Quadrivalent [flu] vaccine eliciting ADEM." *Id.* at 6. He reiterated his previously stated position that the flu vaccine is not associated with encephalitis, and that a more likely cause for Petitioner's condition is an infectious process. *Id.* at 6–7. Dr. Tompkins concluded that

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[30] Baxter, *surpa* note 13.

[31] Bhavarth Shukla et al., *Aseptic Meningitis in Adults and Children: Diagnostic and Management Challenges*, 94 J. CLINICAL VIROLOGY 110 (2017).

[32] Mohammed A. Aldriweesh et al., *Viruses Causing Aseptic Meningitis: A Tertiary Medical Center Experience with a Multiplex PCR Assay*, 11 FRONTIERS NEUROLOGY 1 (2020).

Petitioner's gastrointestinal symptoms and proximity to individuals with URI symptoms provides the best evidence for a viral cause. *Id.* at 8. Furthermore, Petitioner's "recovery from encephalitis following the intravenous antibiotics and antiviral drug treatment suggest resolution of an infectious process causing the acute meningoencephalitis." *Id.* Dr. Tompkins asserted that "many if not a majority of infection encephalitis cases remain undiagnosed," but in Petitioner's case, "the medical records provide compelling evidence of an . . . infection [as] the most likely cause of [Petitioner's] acute meningoencephalitis." *Id.*

IV. Applicable Legal Standards

I am resolving Petitioner's claim on the filed record. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where, in the exercise of their discretion, they conclude that doing so will properly and fairly resolve the case. *See* 42 U.S.C. § 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of a hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided cases on the papers in lieu of hearing and those decisions were upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs.*, 38 Fed. Cl. 397, 402–03 (1997) (determining that the special master acted within his discretion in denying an evidentiary hearing); *Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993); *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

To receive compensation under the Vaccine Act, a petitioner must demonstrate either that: (1) the petitioner suffered a "Table injury" by receiving a covered vaccine and subsequently developing a listed injury within the time frame prescribed by the Vaccine Injury Table set forth at 42 U.S.C. § 300aa-14, as modified by 42 C.F.R. § 100.3; or (2) that petitioner suffered an "off-Table injury," one not listed on the Table, as a result of receiving a covered vaccine. *See* 42 U.S.C. §§ 300aa-11(c)(1)(C); *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1319–20 (Fed. Cir. 2006). In this case, Petitioner does not allege a Table injury and must prove that her injury was caused-in-fact by a Table vaccine.

To establish causation-in-fact, a petitioner must demonstrate by a preponderance of the evidence that the vaccine was the cause of the injury. 42 U.S.C. § 300aa-13(a)(1)(A). A petitioner is required to prove that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321–22 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)).

In the seminal case of *Althen v. Sec'y of the Dept. of Health & Hum. Servs*, the Federal Circuit set forth a three-pronged test used to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. 418 F.3d 1274, 1278–79 (Fed. Cir. 2005). In *Broekelschen v. Sec'y of Health and Hum. Servs.*, the Federal Circuit recognized that in some circumstances, the special master may "first determine which injury was best supported by the evidence in the record before applying the *Althen* test." 618 F.3d 1339, 1346 (Fed. Cir. 2010). This principle also means that a petitioner must establish that the vaccinee suffers the injury allegedly linked to the vaccination. *Lombardi v. Sec'y of Health & Hum. Servs.,* 656 F.3d 1343, 1353–54 (Fed. Cir. 2011).

The *Althen* test requires petitioners to set forth: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278. To establish entitlement to compensation under the Program, a petitioner is required to establish each of the three prongs of *Althen* by a preponderance of the evidence. *Id.* "[C]lose calls regarding causation are resolved in favor of injured claimants." *Id.* at 1280. Further, evidence used to satisfy one prong of the test may overlap to satisfy another prong. *Capizzano,* 440 F.3d at 1326.

Under the first prong of *Althen*, a petitioner must offer a scientific or medical theory that answers in the affirmative the question: "can the vaccine[] at issue cause the type of injury alleged?" *See Pafford v. Sec'y of Health & Hum. Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *mot. for rev. denied*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 548–49. Petitioners are not required to identify "specific biological mechanisms" to establish causation, nor are they required to present "epidemiologic studies, rechallenge[] the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities." *Capizzano,* 440 F.3d at 1325 (quoting *Althen*, 418 F.3d at 1280). Scientific and "objective confirmation" of the medical theory with additional medical documentation is unnecessary. *Althen*, 418 F.3d at 1278–81; *see also Moberly*, 592 F.3d at 1322. However, as the Federal Circuit has made clear, "simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) (citing *Moberly*, 592 F.3d at 1322). Indeed, the Federal Circuit has "consistently rejected theories that the vaccine only 'likely caused' the injury and reiterated that a 'plausible' or 'possible' causal theory does not satisfy the standard." *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, (Fed. Cir. 2019) (citing *Moberly*, 592 F.3d at 1322 and *LaLonde*, 746 F.3d at 1339). Rather, "[a] petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case." *Moberly*, 592 F.3d at 1322. In general, "the statutory standard of preponderance of the evidence requires a petitioner to demonstrate that the vaccine more likely than not caused the condition alleged." *LaLonde,* 746 F.3d at 1339.

Furthermore, establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of her claim. *Lampe v.*

Sec'y of Health & Hum. Servs., 219 F.3d 1357,1361 (Fed. Cir. 2000). The Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), requires that courts determine the reliability of an expert opinion before it may be considered as evidence. However, in the Vaccine Program, the *Daubert* factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("[U]niquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted."); *see also Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the

> factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

The *Daubert* factors are "meant to be helpful, not definitive." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 151 (1999). The factors do not "constitute 'a definitive checklist or test'" and may be applied differently depending on the facts of a particular case. *Id.* at 150 (quoting *Daubert*, 509 U.S. at 593).

"In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Daubert*, 509 U.S. at 590 (citation omitted). Thus, for Vaccine Act claims, a "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. Nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 743 (2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *see also D'Tiole v. Sec'y of Health & Hum. Servs.*, No. 15-085V, 2016 WL 7664475, at *24 (Fed. Cl. Spec. Mstr. Nov. 28, 2016) (stating that the Vaccine Act "require[s] a chain of reliable propositions supporting [a] petitioner's theory").

Under the second prong of *Althen*, a petitioner must prove that the vaccine actually did cause the alleged injury in a particular case. *See Pafford*, 2004 WL 1717359, at *4; *Althen*, 418 F.3d at 1279. The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A petitioner does not meet this obligation by showing only a temporal association between the vaccination and the injury; instead, the petitioner "must explain *how* and *why* the injury occurred." *Pafford*, 2004 WL 1717359, at *4 (emphasis in original). The special master in *Pafford* noted petitioners "must prove [] both that her vaccinations were a substantial factor in causing the illness . . . and that the harm would not have occurred in the absence of the

vaccination." 2004 WL 1717359, at *4 (citing *Shyface*, 165 F.3d at 1352). A reputable medical or scientific explanation must support this logical sequence of cause and effect. *Hodges v. Sec'y of Health & Hum. Servs.,* 9 F.3d 958, 961 (Fed Cir. 1993) (citation omitted). Nevertheless, "[r]equiring epidemiologic studies . . . or general acceptance in the scientific or medical communities . . . impermissibly raises a claimant's burden under the Vaccine Act and hinders the system created by Congress . . . ." *Capizzano*, 440 F.3d at 1325–26. "[C]lose calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280.

In Program cases, contemporaneous medical records and the opinions of treating physicians are favored. *Capizzano*, 440 F.3d at 1326 (citing *Althen*, 418 F.3d at 1280). Indeed, when reviewing the record, a special master must consider the opinions of treating physicians. *Capizzano*, 440 F.3d at 1326. This is because "treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Id.* In addition, "[m]edical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). While a special master must consider these opinions and records, they are not "binding on the special master or court." 42 U.S.C. § 300aa-13(b)(1). Rather, when "evaluating the weight to be afforded to any such . . . [evidence], the special master . . . shall consider the entire record . . . ." *Id.*

To satisfy the third *Althen* prong, a petitioner must establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan*, 539 F.3d at 1352. Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id.* However, "cases in which onset is too soon" also fail this prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id.*; *see also Locane v. Sec'y of Health & Hum. Servs.*, 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

Although a temporal association alone is insufficient to establish causation, under the third prong of *Althen*, a petitioner must show that the timing of the injury fits with the causal theory. *See Althen*, 418 F.3d at 1278. The special master cannot infer causation from temporal proximity alone. *See Thibaudeau v. Sec'y of Health & Hum. Servs.*, 24 Cl. Ct. 400, 403–04 (1991); *see also Grant*, 956 F.2d at 1148 ("[T]he inoculation is not the cause of every event that occurs within the ten[-]day period . . . [w]ithout more, this proximate temporal relationship will not support a finding of causation." (quoting *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983))).

A petitioner who satisfies all three prongs of the *Althen* test has established a prima facie showing of causation. *Hammitt v. Sec'y of Health & Hum. Servs*., 98 Fed. Cl. 719, 726 (2011). A

petitioner who demonstrates by a preponderance of the evidence that she suffered an injury caused by vaccination is entitled to compensation unless the respondent can demonstrate by a preponderance of the evidence that the injury was caused by factors unrelated to the vaccination. *See Althen*, 418 F.3d at 1278; *Knudsen,.*, 35 F.3d 543at 547.In such a case, the government must not merely prove the existence of an alternative cause, but that such an alternative actually caused the injury. *Knudsen,* 35 F.3d at 549. Consequently, when and if the petitioner establishes a prima facie case, the burden then shifts to the government to prove that an alternative cause, unrelated to the administration of the vaccine, was the "sole substantial factor" in causing the alleged injury. *See de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1354 (Fed. Cir. 2008); *see also Hammitt*, 98 Fed. Cl. at 726 (explaining that the respondent's burden is to show that the "factor unrelated" was the "sole substantial factor" in causing the injury). Additionally, a factor unrelated "may not include 'any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness or condition.'" 42 U.S.C. § 300aa-13(a)(2); *see also Doe v. Sec'y of Health & Hum. Servs.*, 601 F.3d 1349 (Fed. Cir. 2010) (stating that an idiopathic diagnosis cannot be a "factor unrelated," as it is idiopathic).

V. Discussion

A. Diagnosis

Petitioner presented to the hospital seven days post vaccination, on January 5, 2018, with symptoms of confusion, nausea, vomiting, abdominal pain, and tremors. Pet'r's Ex. 3 at 29. She further complained of high fever and deliriousness that began the previous day. *Id.* On January 7, 2018, Petitioner was seen by a geriatric specialist, whose preliminary impression included a notation to "rule out infectious meningoencephalitis," and who opined that Petitioner's "persistent fever curve [was] more suggestive of CNS fever." *Id.* at 38. Throughout Petitioner's hospitalization, multiple treaters sought to determine her condition's etiology, but there is no evidence that they ever considered ADEM or any other demyelinating disorder as a differential diagnosis. *See id.* at 5. Petitioner's expert neurologist, Dr. Schenk, originally opined that ADEM was "the most acceptable diagnosis" to consider despite her presentation's divergence with a typical ADEM clinical course. Pet'r's Ex. 15 at 18. Dr. Schenk provided a comprehensive explanation of the symptoms, progression, and diagnosis of ADEM in support of his assertion. *Id.* 11–18. It is not necessary, however, to consider Dr. Schenk's argument on this matter, because in a subsequent report, Dr. Schenk modified his opinion. Pet'r's Ex. 16 at 2. He noted that Petitioner's MRI and CSF profile did not support an ADEM diagnosis and described her case as atypical. *Id.* Despite his acknowledgment that common ADEM treatments were not administered and did not factor into her dramatic and rapid recovery, he maintained that ADEM was a potential differential diagnosis. *Id.* Ultimately, he conceded that meningoencephalitis was the correct diagnosis, and it was much less likely that Petitioner suffered from an acute demyelinating event such as ADEM. *Id.* Respondent's expert, Dr. Wilson, agreed with the infectious meningoencephalitis diagnosis from Petitioner's hospitalization. Resp't's Ex. B at 3. He identified the inconsistencies between Petitioner's condition and what is commonly seen in ADEM patients. *Id.* Presently, there is no material dispute as to Petitioner's meningoencephalitis diagnosis, but Petitioner and Respondent do dispute whether her condition is due to a vaccine-initiated, autoimmune response or an unidentified infection. Notwithstanding the agreement on Petitioner's underlying condition, it is important to note how Petitioner's theory of injury has evolved. Dr. Schenk's opinion is directly

at odds with Dr. Wilson's, and their respective expertise on the nature of Petitioner's condition and its pathogenesis cannot be separated from the ability to correctly diagnose her condition as a preliminary matter. I find that there is preponderant evidence that Petitioner suffered from meningoencephalitis.

B. *Althen* Prong One – Medical Theory

The biological mechanism in this case is initially presented by Dr. Schenk but expanded on by Dr. Ramos, a geriatric specialist with expertise in allergy and immunology. *See* Pet'r's Ex. 15; Pet'r's Ex. 17. In his first report, Dr. Schenk described a cross-reaction process wherein proteins that protect and support the function of the myelin sheath in the CNS are attacked by antiviral antibodies or a cell-mediated response and cause neurological dysfunction. Pet'r's Ex. 15 at 1. This theory is specific to neurological conditions, but it is only relevant to conditions that include demyelination. While demyelination does occur in some cases of meningoencephalitis, the lack of demyelination in the present case was a key factor in determining Petitioner's diagnosis. In Dr. Schenk's second report, he conceded that it is less likely that Petitioner suffered from an atypical ADEM case, but he maintained that her flu vaccine "appeared to be a contributing factor to the development of a delayed meningoencephalitis." Pet'r's Ex. 16 at 2. Dr. Schenk did not expound further on the biological mechanism but noted that he "agree[d] with Dr. Cristina Ramos' reported observations and defer[ed] to the evidence included in the details of the theory included in [her] report." *Id.* at 1.

Dr. Ramos identified molecular mimicry and immune cross-reaction as a "possible and viable explanation of how vaccines may cause neurological disease." Pet'r's Ex. 17at 8. Dr. Ramos described the general theory of cross-reactivity due to structural homology between pathogens and self-antigens. *Id.* She then asserted that "molecular mimicry has been widely accepted as a proven concept and is considered to be one of the mechanisms in which viral or bacterial infection can result in the development or worsening of autoimmune disease." *Id.* at 9. Specifically, Dr. Ramos discussed molecular mimicry in the context of GBS and narcolepsy following flu vaccines. *Id.* at 10–11. She also discussed case reports of encephalitis following rabies and Japanese encephalitis vaccines. *Id.* at 11. Although she discussed a possible link between vaccines and the category of neurological disease, Dr. Ramos did not articulate a theory that links the flu vaccine administered in this case to meningoencephalitis. Indeed, her entire general causation argument could be inserted into any case that alleges any vaccine caused any autoimmune disease. *See Dennington v. Sec'y of Health & Hum. Servs.*, 167 Fed. Cl. 640 (Fed. Cl. Sept. 20, 2023), *appeal withdrawn*, No. 2024-1214 (Fed. Cir. 2024). In addition to molecular mimicry, Dr. Ramos also briefly mentioned bystander activation, epitope spreading, and polyclonal activation. *Id.* at 10. However, she did not explain how one or more of these processes worked to form a chain of reliable propositions supporting vaccine causation. Dr. Ramos highlighted a study that found increased autoantibody levels post flu vaccination, but she was unable to articulate any clinical significance or relevance to encephalitis pathogenesis. *Id.* at 11 (citing Pet'r's Ex. 17-27). Drs. Schenk and Ramos identified medical theories, but did not persuasively explain how these offered mechanisms of vaccine causation are relevant to this case. Accordingly, Petitioner has not presented preponderant evidence of a sound and reliable medical theory connecting the flu vaccine to meningoencephalitis.

C. *Althen* Prong Two – Actual Causation

Upon presentation to the hospital, Petitioner was treated with broad spectrum antibiotics and antiviral therapies, despite her physicians' inability to identify a particular infectious agent. Pet'r's Ex. 3 at 39–40, 45. Petitioner was continued on this treatment as testing for West Nile, CMV, HSV, and Enterovirus came back negative, and her condition improved. *Id.* at 103. Petitioner's symptoms were severe and required life-saving treatments, including ICU care and intubation. *Id.* at 32. Approximately six days into her hospitalization, or around January 11, 2018, Dr. Butler questioned the potential effect of Petitioner's vaccination on her condition. Pet'r's Ex. 5 at 20. Her treaters explored many possible causes but ultimately proceeded as though her condition had an infectious etiology. *Id.* This is further reflected in her discharge diagnosis on January 16, 2018, which notes a possible viral cause, but no relationship to her flu vaccine. Pet'r's Ex. 3 at 119. Dr. Miljkovic saw Petitioner for follow up at the end of January and agreed with Petitioner's encephalitis diagnosis but was unclear on the etiology noting possibly viral versus post vaccination. Pet'r's Ex. 9 at 4. Petitioner was later seen by Dr. Barasch, who also agreed with her discharge diagnosis. Pet'r's Ex. 5 at 19. Following assessment, she recorded Petitioner's condition as viral encephalitis. *Id.* at 14. The mention and consideration of a possible relationship between her vaccination and meningoencephalitis illustrates that Petitioner's treaters were open and dedicated to determining the cause of her symptoms. That does not mean that they believed her condition to be more likely than not caused by the flu vaccine. In fact, although more than one of her treaters concluded that her encephalitis was viral, any mention of vaccine causation was tied to the temporal relationship or noted as a possibility.

Petitioner's inability to meet her burden of articulating a general theory of causation is fatal to her claim, but the strongest evidence in support of dismissal is her own expert's statements regarding actual causation. In her first expert report, Dr. Ramos opined that "we have already established that it is more likely that [Petitioner's] symptoms were caused by an infection." Pet'r's Ex. 17 at 7. She added that the temporal relationship between vaccination and symptom onset creates the possibility of vaccine causation. *Id.* 7–8. However, the plain meaning of Dr. Ramos' former statement precludes any finding that it is more likely than not Petitioner's symptoms were caused by her vaccine. Evidence of mere possibility is not enough. Dr. Ramos went on to assert that there was "sufficient evidence to support the conclusion that [Petitioner's] symptoms were caused by the [flu] vaccine." *Id.* at 13. Dr. Ramos did not simply say that Petitioner's symptoms were caused by the flu vaccine. Then, in her supplemental report, Dr. Ramos again undercut Petitioner's ultimate contention and stated that she "cannot in sound medical judgement state that vaccination is the most probable cause of [Petitioner's] neurological presentation." Pet'r's Ex. 18 at 2. Dr. Ramos offered a disclaimer, noting that "we cannot in all certainty exclude the possibility that [Petitioner's] symptoms were caused by the vaccine." *Id.* However, that is not the standard for establishing any fact within the Program. Again, it is curious how Dr. Ramos reconciled her medical judgment with her later opinion that "a vaccine related adverse event following the [flu] vaccine is a more probable cause of [Petitioner's] symptoms." *Id.* Considering Petitioner's complete medical record and that Petitioner's own immunologist is unable to attribute her condition to vaccination, I do not find there is preponderant evidence that Petitioner's meningoencephalitis was vaccine caused.

D. *Althen* Prong Three – Temporal Relationship

Drs. Schenk and Ramos both relied heavily on the timing of Petitioner's symptoms in support of vaccine causation. *See* Pet'r's Ex. 15; Pet'r's Ex. 17. Petitioner's experts focused their opinions on ADEM and argued that Petitioner's symptom manifestation approximately one week post vaccination was strong evidence of causation. However, both experts conceded that ADEM is likely not the proper diagnosis, and I have found that there is no preponderant evidence of this condition in the record. Therefore, a timeline for vaccine-caused ADEM would be analogous at best. Instead, the medical records, which are favored and presumed trustworthy, are determinative here. During Petitioner's hospitalization and follow up, multiple treaters noted that the timing of her symptoms was consistent with vaccine-caused encephalitis. It appeared to be the driving factor for consideration of a vaccine etiology after testing did not reveal a specific infectious cause. Therefore, despite Petitioner's lack of preponderant evidence of a biological mechanism linking flu vaccine to meningoencephalitis, I find there is preponderant evidence of an appropriate temporal relationship between her vaccination and the onset of symptoms approximately seven days later. This relationship is insufficient however, to cure the evidentiary shortcomings under *Althen* prongs one and two. *See Grant,* 956 F.2d at 1148 ("Temporal association is not sufficient, however, to establish causation in fact.").

VI. Conclusion

After a careful review of the record, Petitioner has failed to prove by preponderant evidence that her injuries, including meningoencephalitis, were caused by her December 29, 2017, flu vaccination. Accordingly, I **DENY** Petitioner's claim and **DISMISS** her petition.[33]

IT IS SO ORDERED.

s/Herbrina D.S. Young
Herbrina D.S. Young
Special Master

[33] Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of a notice renouncing the right to seek review.